

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

ROLAND C. MRACEK,

Plaintiff,

v.

BRYN MAWR HOSPITAL, and
INTUITIVE SURGICAL, INC.,

Defendants.

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CIVIL ACTION

No. 08-296

MEMORANDUM

ROBERT F. KELLY, Sr. J.

MARCH 11, 2009

Roland C. Mracek (“Mracek”) brought this action against Bryn Mawr Hospital and Intuitive Surgical, Inc. (“Intuitive”) for damages arising out of strict product liability, strict malfunction liability, negligence, and breach of warranty in connection with a prostatectomy¹ performed with an operative robot called the “da Vinci” which was manufactured by Intuitive. Presently before this Court is a Motion for Summary Judgment filed by Intuitive. For the reasons set forth below, the Motion is granted with regard to all causes of action.

I. BACKGROUND

In October 2004, Mracek had a prostate biopsy performed which resulted in positive results for adenocarcinoma² of the prostate. Thereafter, in January 2005, Mracek met with Dr. David McGinnis of the Bryn Mawr Urology Group to discuss his options of treatment. Mracek

¹Prostatectomy- surgical removal of the prostate or a part of it. Dorland’s Illustrated Medical Dictionary, Twenty-eighth Edition, at 1366 (1994) (“Dorland’s”).

²Adenocarcinoma- carcinoma derived from glandular tissue or in which the tumor cells form recognizable glandular structures. Dorland’s at 25.

asserts that he informed Dr. McGinnis that he did not suffer with erectile dysfunction, and was quite concerned about erectile dysfunction being a result of any treatment of his prostate cancer. Mracek met again with Dr. McGinnis on March 31, 2005, at which time, Dr. McGinnis informed him that the da Vinci surgical robot (“robot”) would be used for the radical prostatectomy, so as to minimize the risk of erectile dysfunction. The surgery was scheduled for June 9, 2005. On this date, Mracek’s surgery began with him being put under general anesthesia while the robot was brought in and readied. According to Mracek’s Complaint, the surgical team, led by Dr. McGinnis, proceeded part way into the surgery, “taking his bladder down,” and “dividing the urachus,”³ when suddenly, the robot starting displaying error messages. The surgical team restarted the robot and was only able to make a small amount of progress before the machine again started displaying error messages. As a result, the surgical team was forced to “undock the robot from its trocars,”⁴ and attempted to restart it several times. They also attempted to place a call to Intuitive’s tech support. A tech representative for the robot subsequently came to the operating room, and attempted to assist the surgical team troubleshoot the problems with the robot, including “repositioning the robot’s arms and multiple redocking of the robot.” It, however, failed to function.

Dr. McGinnis made a final attempt to use the robot by trying to use the robotic arm to run

³Urachus- a canal in the fetus that connects the urinary bladder with the allantois; it persists throughout life as a fibrous cord into which a patent canal may extend for part of the distance to the umbilicus. Dorland’s at 1777.

⁴Trocar- a sharp-pointed instrument equipped with a cannula, used to puncture the wall of a body cavity and withdraw fluid. Dorland’s at 1748.

the camera while he did the rest of the surgery laparoscopically.⁵ This attempt, however, failed when the machine would not allow the team to manually reposition the arm. As a result of the machine's malfunction, the surgical team abandoned its attempt at a robotic prostatectomy, and brought in the laparoscopic equipment to finish the surgery. Between the time the team abandoned use of the robot and the time the laparoscopic equipment was brought in and utilized, approximately forty-five (45) minutes had elapsed.

One week after the surgery was completed laparoscopically, Mracek was readmitted to the hospital due to a gross hematuria that occurred while he was in a public restroom, which required his daughter to assist him getting to the hospital while blood was pouring out of his genitals. Mracek now contends that, as a direct result of the delay and subsequent laparoscopic procedure, he now suffers from total erectile dysfunction, and suffers daily abdominal pain which prevents him from comfortably sleeping or sitting for an extended period of time. Mracek subsequently filed suit against the Defendants⁶ for strict products liability, negligence, breach of warranty, and strict malfunction liability in the Court of Common Pleas of Philadelphia. The matter was then removed to this Court on January 17, 2008.

II. STANDARD OF REVIEW

Federal Rule of Civil Procedure 56(c) states that summary judgment is proper "if there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter

⁵Laparoscope- an instrument comparable to an endoscope which, when inserted into the peritoneal cavity, permits it to be inspected. Dorland's at 900.

⁶Defendant, Bryn Mawr Hospital, was voluntarily dismissed from this action by Order of the Court of Common Pleas of Philadelphia on December 21, 2007. Thus, Intuitive remains the sole defendant in this action before us.

of law.” See also Hines v. Consol. Rail Corp., 926 F.2d 262, 267 (3d Cir. 1991). The Court asks “whether the evidence presents a sufficient disagreement to require submission to the jury or whether . . . one party must prevail as a matter of law.” Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 251-52 (1986). The moving party has the initial burden of informing the court of the basis for the motion and identifying those portions of the record that demonstrate the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). “A fact is material if it could affect the outcome of the suit after applying the substantive law. Further, a dispute over a material fact must be ‘genuine,’ i.e., the evidence must be such ‘that a reasonable jury could return a verdict in favor of the non-moving party.’” Compton v. Nat’l League of Prof’l Baseball Clubs, 995 F. Supp. 554, 561 n.14 (E.D. Pa. 1998).

Summary judgment must be granted “against a party who fails to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial.” Celotex, 477 U.S. at 322. Once the moving party has produced evidence in support of summary judgment, the non-moving party must go beyond the allegations set forth in its pleadings and counter with evidence that presents “specific facts showing that there is a genuine issue for trial.” Fed. R. Civ. P. 56(e); see Big Apple BMW, Inc. v. BMW of N. Am. Inc., 974 F.2d 1358, 1362-63 (3d Cir. 1992). “More than a mere scintilla of evidence in its favor” must be presented by the non-moving party in order to overcome a summary judgment motion. Tziatzios v. United States, 164 F.R.D. 410, 411-12 (E.D. Pa. 1996). If the court determines that there is no genuine issues of material fact, then summary judgment will be granted. Celotex, 477 U.S. at 322.

III. DISCUSSION

1. Strict Products Liability

Intuitive asserts that, since Mracek has failed to submit any expert report that is critical of the da Vinci robot, he cannot meet his burden of proof with respect to any of the theories of liability that he has asserted, including strict liability. We agree, and find that summary judgment should be granted for several reasons, as will be discussed infra.

In Webb v. Zern, 220 A.2d 853, 854 (Pa. 1966), the Pennsylvania Supreme Court adopted § 402A of the Restatement (Second) of Torts as the law of strict products liability in Pennsylvania.⁷ The Court subsequently established that § 402A "imposes strict liability in tort not only for injuries caused by the defective manufacture of products, but also for injuries caused by defects in their design." Lewis v. Coffing Hoist Div., Duff-Norton Co., 528 A.2d 590, 592 (Pa. 1987). In order to bring a products liability action in Pennsylvania, a plaintiff must demonstrate that: (1) the product was defective; (2) the defect existed while the product was in the control of the manufacturer; and (3) the defect was the proximate cause of the plaintiff's

7. Section 402A of the Restatement (Second) of Torts (1965) provides that:

(1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer . . . is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if (a) the seller is engaged in the business of selling such a product, and (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.

(2) The Rule stated in subsection (1) applies although (a) the seller has exercised all possible care in the preparation and sale of his product, and (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

injuries. Walton v. Avco Corp., 610 A.2d 454, 458-59 (Pa. 1992).

As noted above, Intuitive argues that Mracek has failed to meet his burden of proof for strict liability because he has not submitted an expert report that is critical of the da Vinci robot. This Circuit has held that expert testimony is not required when the matter under consideration is simple and a lack of ordinary care is obvious and within the range of comprehension of the average juror. Oddi v. Ford Motor Co., 234 F.3d 136, 159 (3d Cir. 2000); Padillas v. Stork-Gamo, Inc., 186 F.3d 412 (3d Cir. 1999). Oddi held that “although expert evidence is generally required in a products liability case where a defect is alleged, we have never foreclosed the possibility that a defective condition may be established through non-expert evidence.” Id. at 159.

Thus, because the absence of expert testimony is not fatal to a products liability case, the proper analysis is whether the asserted defect is obvious enough to be ascertainable by the average juror without speculation. Mracek contends that an expert report is not necessary because the surgeon who performed his operation, Dr. McGinnis, will testify at trial concerning not only his pre and postoperative medical condition, but also the malfunction of the da Vinci robot. Mracek maintains that the defect of the surgical robot is obvious because all of its component parts shut down after repeatedly flashing “error” messages, and then was not able to be restarted once the surgery commenced. Mracek argues that it is not necessary for him to produce an expert report for a finding of an obvious defect, as such a defect is not beyond the purview of a layperson when presented with this factual record. Intuitive asserts that the average juror does not have the requisite background to adjudicate and reach a conclusion as to whether the machine was defective, and such a lack of expert testimony would only lead to jury

speculation.

Our Circuit's decisions in Padillas and Oddi guide our analysis. In Padillias, the court found that a juror could look at a chicken cutter with exposed blades and determine whether it was defective for not having a guard to cover the blades. Padillias, 186 F.3d at 415-16. In Oddi, the court granted summary judgment to the defendant because it found that a juror could not look at a bread truck and reasonably conclude whether a bumper was defective without expert testimony. Oddi, 234 F.3d at 159-60. The Court explained that the truck Oddi was driving is not at all like the chicken cutter with exposed blades in Padillas. A whirling cutting blade without a proper guard is obviously dangerous. It could reasonably be regarded by a lay juror as a design defect. The Court added that "[W]e do not believe that a juror could look at the front bumper and the flooring of the cab of the truck Oddi was driving and reasonably conclude, not only that its design was defective, but also that testing would have disclosed the defect and that it could have been remedied. Such conclusions are within the peculiar competence of experts. Id.

We are of the opinion that the instant case is more akin to Oddi than Padillias. Here, Mracek asserts that the defect in the da Vinci robot is obvious because it displayed error message and had to be shut down during the operation. We disagree. It is apparent that the da Vinci is a complex machine, one in which a juror would require the assistance of expert testimony in order to reasonably determine if the robot had a defect. A surgical assistant robot is a more technical and complex machine than even the car bumper in Oddi. Mracek has only submitted the operative report of Dr. McGinnis in defense of this summary judgment motion. In such, Dr. McGinnis give a narrative of the robot failing to function properly, but he does not opine that the

robot has a defect.⁸ For all we know at this stage of this litigation, Dr. McGinnis could have used that same da Vinci robot in dozens of previous operations without any trouble. Mracek asserts that McGinnis will be subpoenaed to testify at trial. However, this does not fulfill his burden of presenting evidence of a defect at this time to withstand summary judgment. McGinnis neither offered an opinion as an expert on the da Vinci in his operative report, nor does Mracek even assert that he is an expert on the working of such. Thus, without an expert report, Mracek cannot establish that the da Vinci robot had a defect under a strict products liability theory.

⁸ Dr. McGinnis stated in this report that:

[We] got part way through taking the bladder down and dividing the urachus when we ran into fault and error messages. We were able to get [it] restarted and get going and our situation improved and we were able to progress some. We had to stop again because of error messages. We undocked the robot from its trocars and restarted it, we actually did this more than 1 time throughout our troubleshooting the robot. We had several phone calls to tech support. Our local representative John Bretanal was not initially in the room but he came into the room as we were troubleshooting and helped with troubleshooting the robot. Initially, it appeared that the yellow robotic arm was malfunctioning. We attempted to put it off to the side, swinging the fourth arm over to the yellow arm side and redocking the robot. However, it would initially function for awhile and then it would not function properly. We again restarted the robot and still were not able to get it to properly function. I wanted to use the robotic camera arm to run the camera for me to do the rest of the case laparoscopically but this would not work either. At this point the robot would not allow us to even manually clutch the camera arm around. I removed the robot completely and or the staff helped me get regular laparoscopic equipment in which included bipolar forceps, some sets of regular laparoscopic instruments and we brought the Esops' into the room, hooked it up to Hermes', docked it to the operating table and got it up and running. We abandoned trying to troubleshoot the da Vinci probably around 10:45 and we got the regular laparoscopic equipment up and running with Esop and so forth probably around 11:30.

(See Resp. Def.'s Mot. Summ. J., Ex.B.)

In addition and even more fatal to Mracek's cause of action for strict products liability is his failure to submit any evidence of causation between what occurred in the operating room with the da Vinci robot and his erectile dysfunction. As noted above, Mracek asserts that Dr. McGinnis will be called to testify at trial concerning the malfunction of the robot and how said malfunction related to the surgery. Mracek also maintains that Dr. Peter Sinaiko, his treating urologist, will testify as to his pre and post operative condition. Mracek argues that a treating physician, who was not retained in anticipation of litigation, is not required to tender a pre-trial expert report in order to testify as to a patient's medical condition at trial. Alwine v. Sugar Creek Rest, Inc., 883 A.2d 605, 610 (Pa Super. 2005); Buss v. Quigg, No. 01- 3908, 2002 WL 32345703, at * 1 (E.D. Pa. Aug. 5, 2002). Mracek argues that he is not required to furnish expert reports on the issue of causation of his injuries in this case because none of the doctors who will testify regarding his pre and/or post operative condition were retained in anticipation of litigation.

Mracek's argument, however, is severely flawed. It is agreed that treating physicians are not required to submit expert reports when testifying based on their examination, diagnosis and treatment of a patient. See Edwards v. Scott Paper Co., 1997 U.S. Dist. LEXIS 7417, *5 (E.D. Pa. May 23, 1997). Thus, Drs. McGinnis and Sinaiko would be able to testify at trial regarding their treatments and diagnoses of Mracek. However, the fact that they can testify at trial regarding such does not relieve Mracek of his burden to produce evidence of causation in defending a motion for summary judgment. Nor, does Mracek produce any authority supporting such a position.

In support of his opposition to summary judgment, as noted above, Mracek has submitted an operative report from Dr. McGinnis which details the surgical procedure and mechanical

problems with the da Vinci robot, but it does not include any causation between the problems with the robot and Mracek's erectile dysfunction. In addition, Mracek produced summaries of office visits to Dr. Sinaiko. A review of these reports, indicate that Dr. Sinaiko never opined in any of them that the surgical problems with the robot caused Mracek's erectile dysfunction. In fact, in a letter dated September 1, 2005 to Dr. McGinnis, Dr. Sinaiko indicated that the surgery was "successful." Dr. Sinaiko wrote, "Mr. Roland Mracek was seen here today. As you know, he had very successful laparoscopic radical prostatectomy several months ago. He is perfectly continent. His only problem at this time is erectile dysfunction." (See Resp. Def.'s Mot. Summ. J., Ex.B, at 7.)

As stated above, summary judgment must be granted "against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Celotex, 477 U.S. at 322. Mracek has failed to produce any evidence of causation,⁹ and thus, summary judgment will be entered against him with regard to this products liability cause of action. Moreover, as will be discussed, infra, Mracek's lack of evidence regarding causation is fatal to his other causes of actions as well.

2. Breach of Warranty

Intuitive, next, claims that Mracek cannot establish a cause of action for breach of warranty. The standards of § 402A of the Restatement (Second) of Torts apply to breach of warranty as well as strict liability. Kridler v. Ford Motor Co., 422 F.2d 1182, 1184 (3d Cir.

⁹In fact, Mracek acknowledges in his Response to the Motion for Summary Judgment that Dr. McGinnis told him that the da Vinci robot would be used for the surgery "so as to minimize the risk of erectile dysfunction." (See Resp. Def.'s Mot. Summ. J., at 3) There is no evidence in this record that had there been no problems with the robot, erectile dysfunction would not have resulted.

1970). The elements of proof required to demonstrate breach of warranty are similar to those required to establish a strict liability action. Simeone v. Bombardier-Rotax GMBH, 360 F. Supp. 2d 665, 680 n. 5 (E.D. Pa. 2005).

Intuitive argues that, for the same reason that Mracek has failed to establish a cause of action for strict products liability, he has failed to do so for breach of warranty. We agree, and again find that for the same reasons that we granted summary judgment for strict products liability, we do so also for breach of warranty.

3. Strict Malfunction Liability

Mracek has also brought a cause of action under a malfunction theory of products liability. In those cases where a plaintiff is unable to produce direct evidence of a product's defective condition, and thus, the precise nature of the product's defect, a plaintiff, in appropriate cases, can rely on the "malfunction theory" of products liability. Woodin v. J.C. Penney Co., 629 A.2d 974, 975 (Pa. Super. Ct.1993), citing Rodgers v. Johnson & Johnson Products, Inc., 565 A.2d 751, 754 (Pa. 1989). This theory permits a plaintiff to prove a defect through circumstantial evidence. Plaintiff may raise a supportable inference of defect through: (1) evidence of the occurrence of a malfunction; (2) evidence eliminating abnormal use; and (3) evidence eliminating reasonable secondary causes for the accident. Id. If such evidence is present, the plaintiff is relieved from demonstrating the precise defect in the product and the trier of fact is permitted to infer the existence of a defect from the malfunction and the negation of abnormal use and other reasonable secondary causes. Id.

Establishing a prima facie case under a malfunction theory does not require a plaintiff to proffer expert testimony to prove how the product was defective or how the defect arose as a

result of actions taken by the manufacturer. Dansk v. Cameron Coca-Cola Bottling Co. Inc., 703 A.2d 489, 498 (Pa. Super. Ct. 1997). Instead, a plaintiff may sustain his burden without articulating a specific defect by producing: (1) circumstantial evidence of a malfunction; and (2) evidence indicating (a) the product was being used as intended or reasonably expected, and (b) the absence of other reasonable secondary causes. Altronics, 957 F.2d at 1105; Dansk, 703 A.2d at 496.

Intuitive argues that summary judgment is appropriate where “based upon [the plaintiff’s] own proof, more than one cause could account for the accident.” Dansk, 703 A.2d at 497, and that Mracek has entirely failed to eliminate any reasonable, secondary causes of the incident giving rise to the Complaint. Intuitive asserts that:

This is a matter of complex surgical innovation— a robotic procedure requiring a multitude of medical decisions and judgments made by the surgeon. The use and timing of various ancillary medical equipment in connection with this innovative and complex procedure reinforces that any number of reasonable secondary causes could or were responsible for the alleged damages.

(Def’s Mot. Summ. J. at 6). We agree.

“Summary judgment is not warranted simply because the defendant hypothesizes (or even presents evidence of) reasonable secondary causes.” Dansk, 703 A.2d at 497. Instead, it is appropriate only where, “based upon the [the plaintiff’s] own proof, more than one cause could account for the accident.” Id. (quoting Shiller v. Milwaukee Elec. Tool Corp., 835 F. Supp. 839, 841 (E.D. Pa. 1993)). Here, Mracek has offered no evidence to eliminate any reasonable secondary causes, and thus, he has failed to meet his burden under the malfunction theory of strict products liability.

In addition, even if such evidence was produced, Mracek is not relieved from submitting

evidence of the other elements of a products liability cause of action. Again, Mracek's lack of evidence with regard to the causation element is also fatal to this cause of action, and summary judgment is appropriate.

4. Negligence

Lastly, Mracek has claimed a cause of action for negligence. A negligence claim may stand even in the absence of a "defect" under strict liability principles. Hittle v. Scripto-Tokai Corp., 166 F. Supp. 2d 142, 152 (M.D. Pa. 2001); Griggs v. BIC Corp., 981 F.2d 1429 (3d Cir. 1992). A prima facie negligence claim requires the plaintiff to show that: (1) the defendant had a duty to conform to a certain standard of conduct; (2) the defendant breached that duty; (3) such breach caused the injury in question; and (4) the plaintiff incurred actual loss or damage. Krentz v. Consol. Rail Corp., 910 A.2d 20, 27-28 (Pa. 2006).

However, again, Mracek has not produced evidence of causation. , and there is no genuine issue of material fact regarding this element of negligence that can be given to a jury. Accordingly, summary judgment is granted as to all Mracek's causes of action.

An appropriate Order follows.

**IN THE UNITED STATES DISTRICT COURT
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ROLAND C. MRACEK,

Plaintiff,

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BRYN MAWR HOSPITAL, and
INTUITIVE SURGICAL, INC.,

Defendants.

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CIVIL ACTION

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ORDER

AND NOW, this 11th day of March, 2009, upon consideration of Defendant, Intuitive Surgical, Inc.'s, Motion for Summary Judgment (Doc. No. 7), and Plaintiff, Roland C. Mracek's, Response and the Exhibits attached thereto, it is hereby **ORDERED** that Defendant's Motion is **GRANTED**.

BY THE COURT:

/s/ Robert F. Kelly
ROBERT F. KELLY
SENIOR JUDGE

